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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/916,977	07/27/2001	Ben C. Askew	20009YDB	9107
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210 7590 03/28/2003

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EXAMINER
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TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

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DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/916,977

Applicant(s)

ASKEW ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7-28-01 (Preliminary Amendment)
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-51 and 53-63 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

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### DETAILED ACTION

This application is a divisional application of 09/ 453,847 filed 12-02-1999. The preliminary amendment was filed at the same time with the filing of the application. In order for it to be considered as part of the original disclosure, applicant must submit a substituted oath referring to both the application and the preliminary amendment. See M.P.E.P 608.04(b).

Claims 1-40 have been cancelled. New claims 41-63 are pending.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**New Matter:** Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The proviso [at the end of definition of Y] in claim 41 excludes certain pyrimidinyl compounds which have no support in the specification. **Even a negative limitation requires description, *Ex Parte Grasselli*, 231 USPQ 393.**

2. **Scope of Enablement:** Claims 41-51, and 53-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the **preparation and use** of the

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claimed compound with R<sup>5</sup> (or R<sup>6</sup>) as a quinolinyl ring {while R<sup>7</sup> and R<sup>8</sup> are hydrogen}, does not reasonably provide enablement for the preparation and use of the remaining compounds (i.e., those with R<sup>5</sup>-R<sup>8</sup> as anything else). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

On page 150, Scheme 26 describes the reaction sequence for making the claimed pyrimidinyl compound with R<sup>5</sup> (or R<sup>6</sup>) as a quinolinyl ring {while R<sup>7</sup> and R<sup>8</sup> are hydrogen – i.e., compound 26-6}. The definitions of R<sup>5</sup>-R<sup>8</sup> allow for a wide range of substituents which would require different starting materials. An entirely different mechanism of action might also be required. Note, in said scheme, the intermediate 5-7 is specific to compound 26-6, but its

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preparation and/or availability is not even disclosed. So, to make compound 26-6, one skilled in the art would have to (first) try to make intermediate 5-7. Thus, imagine the extensive trials and errors needed to make intermediates with groups recited for  $R^5$ - $R^8$  !!! Each functional group, ring, or ring system has different solubility, pH, and reacts differently under certain temperature, pressure, etc. Some group might even need a protecting group. The disclosure does not even provide a generic teaching for suitable solvents, temperature range, pH, catalysts, etc. The state of the art as evident by **Duggan et. al.** (WO 98/18461) also provides very limited guidance for the coupling of a substituted pyrimidinyl compound with a Ph-SO<sub>2</sub>NH-amino-ester side chain. Thus, given the scope of  $R^5$ - $R^8$  and the limited guidance, one skilled in the art will have to carry out undue experimentation to make compounds with one of  $R^5$ - $R^8$  as anything other than a quinolinyl ring.

Since it appears that only one pyrimidinyl compound was made (i.e., compound 26-6), and presumably tested, there is insufficient evidence to conclude that other compounds would share the same activity. There is nothing in the specification to correlate the activity of compound 26-6 with the range of compounds claimed herein. Thus, given the unpredictable nature of the art, and the vast number of compounds claimed herein, one skilled in the art will have to carry out undue experimentation to figure out which compounds possess said activity.

Regarding enablement for in chemical cases, the M.P.E.P. explicitly states that:

...in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F. 2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving

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unpredictable factors, such as most **chemical reactions** and **physiological activity**, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)...See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ 2d 1438, 1445 (Fed. Cir. 1991). This is because it is **not obvious** from the disclosure of one species, what other species will work. {M.P.E.P. 2164.03}

Thus while working examples are not needed, to enable a broad genus, the specification must provide more guidance than just the preparation and activity of a single compound.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 43-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 depends on claim 44, and vice versa. Thus, it is not clear what set of compounds is intended. Claims 45-51 are rejected as being (ultimately) dependent on claim 44 with an unclear intended scope.

### ***Double Patenting***

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 41-51 and 53-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, and 9-16 of copending Application No. 09/ 767,471. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of formula (I) in the copending application 09/ 767,471 embraces the scope of the formula claimed herein, particularly when X is pyrimidinyl, and Y is  $(CH_2)_m$ .

It is noted that there is a restriction in 09/ 767,471, and the elected group does not include compounds with X as a pyrimidinyl ring. However, the non-elected group in said application has not been cancelled yet. Thus, at present, the overlapping subject matter still exists.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Claim Objections***

5. Claim 52 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every other Sunday (starting from 3-15-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



***Tamthom N. Truong***  
***Examiner***  
***Art Unit 1624***

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March 23, 2003